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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,385

01/12/2007

Michael Glen Orchard

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EXAMINER

MABRY, JOHN

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

07/30/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,385	Applicant(s) ORCHARD, MICHAEL GLEN	
	Examiner JOHN MABRY	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-4,6,7 and 23-38 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 24-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/12/10; 7/20/10</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to Applicant's Remarks

Election/Restriction dated 12/30/09 has been received and duly noted. The Examiner acknowledges Applicants' election of Group I without traverse. Examiner responded to Applicant's remarks regarding restriction requirement dated 4/9/10.

Thus, the restriction requirement is deemed proper and **FINAL**.

Applicant's response on 7/12/10 filed in response to the Office Action dated 4/9/10 has been received and duly noted.

In view of this response, the status of the rejections/objections of record is as follows:

Status of the Claims

Claims 1-4, 6 and 23 are pending and rejected.

Claims 5 and 8-22 have been cancelled.

Claims 7 and 24-38 are directed towards non-elected subject matter.

35 USC § 112 Rejection(s)

The 112-1st rejection regarding the terms “prodrug” has been overcome in view of Applicant’s amendments to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The two rejections of claim 23 and claims 1-4, 6 and 23 are rejected under 35 are maintained under 35 U.S.C. 103(a) as being unpatentable over WO 02/055498 (PTO-1449).

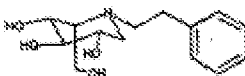
Applicant argues that Examiner used hindsight since the compound of Example 15 of WO '498 is presented as a protected intermediate. Examiner respectfully disagrees with Applicant's allegation. Applicant is simply claiming only a compound. Applicant argues the intended use for the compound of WO '498 compared to compounds of the claimed invention. Compounds of Formula I are being examined; Applicant's intended use of such compounds is irrelevant (see MPEP § 2112 - § 2112.02). However, Examiner will address Applicant arguments as follows:

Applicant argues that Examiner used hindsight since the compound of Example 15 of WO '498 is presented as a protected intermediate. It is not the intention of WO '498 to use compound of Example 15 as a biologically active compound nor was it the intended use of the Applicant's claimed "protected compounds/intermediates". WO '498 removes the protecting groups of similar compounds and tests such compounds for biological activity (see Tables 1 and 2 on page 27). WO '498 also claims to use claimed compounds to treat glycolipid storage diseases such as Gaucher disease, Sandhoffs disease, Tay-Sachs disease, Fabry disease and GM1 gangliosidosis; the treatment of Niemann-Pick disease type C, mucopolysaccharidosis type I,

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mucopolysaccharidosis type IIID, mucopolysaccharidosis type IV; the treatment of neuronal cancer including neuroblastoma, brain cancer, renal adenocarcinoma, malignant melanoma, multiple myeloma and multi-drug resistant cancers; the treatment of Alzheimer's disease, epilepsy, stroke, Parkinson's disease or spinal injury; and the treatment of disease caused by infectious microorganisms which utilize glycolipids just to name a few (see claims 10-20 on pages 29-30). The prior art of WO '498 is in alignment with that of the compounds of the claimed invention. According to the Specification, Applicant does not use or even intend to use claimed "protected" compounds to treat anything nor tests for biological activities of said claimed compounds see Applicant's "unprotected" compounds on pages 10-12, Examples 1 and 2 of the Specification). Additionally, WO '498 did not intend for the -CH₂-Ph-4-OCH₃ bonded to the nitrogen of Example 15 to be a protecting group; only the -Bn protecting groups of the hydroxyls on the periphery of the piperidinyll ring.

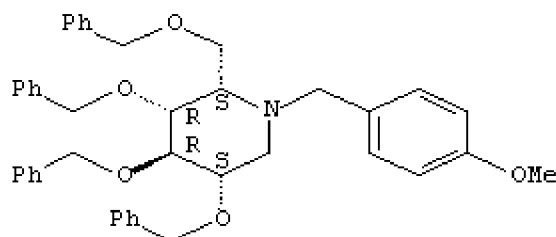
Applicant also argues that the instant invention differs from that of WO '498 by pointing out and arguing compound of Example 9 - see below:



- The compound sharing most structural features with the compounds of claim 1 of the instant patent application would therefore rather be the compound of example 9 of WO '498, which is not a protected intermediate unlike the compound of example 15 of WO '498. The compound of example 9 differs from the compounds of claim 1 of the instant patent application in that:
 - it has a phenethyl-derived side chain instead of a benzyl-derived side chain on the nitrogen atom of the iminosugar core; and
 - the phenyl ring of the iminosugar side chain is unsubstituted, whereas it bears a C_{4,5} alkoxy side chain in 4 position in the compounds of claim 1 of the instant patent application.

Firstly, Examiner is charged with the responsibility to determine what is or what is not the most relevant and closest prior art to apply towards rejection of elected invention. Secondly, Examiner has used Example 15 in the obviousness argument against the elected invention and clearly set forth proper analysis regarding claims 1-4, 6 and 23 (see the following as described in Non-Final dated 4/9/10):

WO '498 discloses compounds of Formulae I and III where P=a protecting group (benzyl) and R=methylphenyl substituted by OR₁ wherein R₁=CH₃ (see Example 15 on page 26).



WO '498 differs with the instant application at the R1 position: WO '498's R1 being C1 versus Applicant's C4-C5. The alkoxy substituent (OR1) on the phenyl group of R teaches C1-C6 alkoxy group (see claim 1 of WO '498).

The MPEP 2144.09 which states: Compounds which are homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH₂- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

WO '498 differs with the instant application at the hydroxyl groups on the piperidiny ring: WO '498's O-P groups versus Applicant's O-H group. However, WO '498 teaches the absence of the protecting groups resulting in just O-H group attached to the piperidiny ring (see Formula I on page 3 through line 40 of page 4).

There were only two differences that Examiner clearly pointed out. Examiner clearly communicated these differences and rationale for why an artisan of ordinary skill would be motivated to make these changes to achieve the instantly claimed invention. Examiner's arguments were also within the obviousness guidelines as set forth by the recent Supreme Court KSR ruling.

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should

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be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) “Obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. See MPEP § 2143 for a discussion

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of the rationales listed above along with examples illustrating how the cited rationales may be used to support a finding of obviousness. See also MPEP § 2144- §2144.09 for additional guidance regarding support for obviousness determinations.

The aforementioned reasons above describe rationales that support a conclusion of obviousness based upon the KSR International Co. v. Teleflex Inc. decision. At least one of letters (A) - (E) rationale is supported above.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections Withdrawn

Obviousness-Type Double Patenting Rejection(s)

Provisional rejection of claims 1-4, 6 and 23 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-10 and 13 of

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copending Application No. 10/522,208 have been withdrawn in view of Examiner's further analysis of claim comparison between said applications.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's primary examiner can be reached at (571) 272-0684, first, or the Examiner's supervisor, Janet Andres, PhD, can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry/
Examiner
Art Unit 1625

/Rita J. Desai/
Primary Examiner, Art Unit 1625